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10/599,855	10/11/2006	Navin N. Thakkar		5789

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INDIA

EXAMINER

MERENE, JAN CHRISTOP L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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06/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,855

Applicant(s)

THAKKAR, NAVIN N.

Examiner

JAN CHRISTOPHER MERENE

Art Unit

3733

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7,8,14,15,18,21,24,27,28,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7,8,14,15,18,21,24,27,28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it appears to have been amended but does not include the proper status identifiers (underlines, crossed out sections) to indicate the amendment. Correction is required. See MPEP § 608.01(b).

Election/Restrictions

2. Newly submitted claims 31-32 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: See Below

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-32 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 7-8, 14-15, 18, 21 24, 27-28, drawn to an implant assembly.

Group II, claim(s) 31-32, drawn to a method of treating a fracture.

4. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The singular element linking the groups together is the intramedullary nail, since such devices are clearly known in the art as shown by Marino US 4,733,654 (Fig 1, 5, abstract), there is no special technical feature shared by both groups .

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **Claims 1, 2-3, 7-8, 14-15, 18, 21, 24, 27** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, part B, the applicant recites "substantially perpendicular defining a plane." It is unclear what is "substantially perpendicular." For examining purposes, the examiner assumes that the distal centerline intersects with the long axis and is substantially perpendicular to the long axis.

10. In claim 14, the applicant recites "connecting end of said intramedullary nail" in line 3. There is insufficient antecedent basis for this limitation in the claim. For examining purposes, the examiner assumes the applicant meant to disclose the connecting end of the targeting device.

11. In Claim 18, the applicant recites: "said sliding hip pin comprises... buttress plate ... contact and early healing." This statement is unclear and indefinite since it appears the applicant is reciting the buttress plate, barrels and large hole are part of the sliding

hip pin. For examining purposes, the examiner assumes that the pin is capable of engaging the large holes and barrels of the buttress plate recited in claim 27.

12. Regarding claim 27, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

In claim 28, part B, the applicant recites "substantially perpendicular defining a plane." It is unclear what is "substantially perpendicular." For examining purposes, the examiner assumes that the distal centerline intersects with the long axis and is substantially perpendicular to the long axis.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

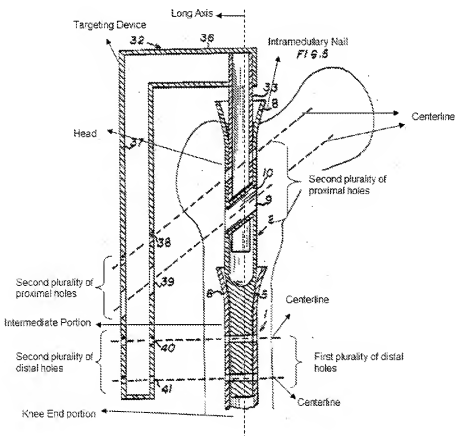
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Marino US 4,733,654.

Marino discloses an implant assembly comprising a unitary intramedullary nail comprising a head, intermediate portion, knee end portion, a long axis with a first plurality of proximal holes and a first plurality of distal holes, each with a centerline that corresponds with a block of second plurality of proximal holes and a block of a second plurality of distal holes of a targeting device connectable to the nail, wherein the proximal centerline intersects the long axis and defines a plane of centre for each of the

plurality of distal holes, the distal centerline intersect the long axis at a substantially perpendicular angle also defining a plane of centre, wherein the plane of centers intersect with each other and where proximal sliding hip pins and distal locking screws is engagable to the proximal and distal holes of the nail, respectfully, without rotating the targeting device. (as seen in Fig below as well as in Fig 1).

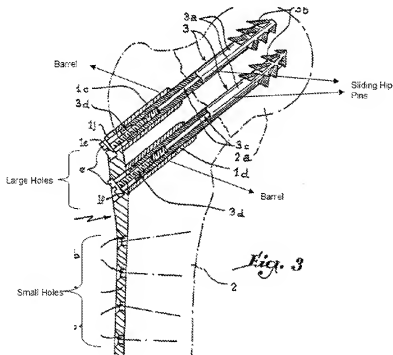


Claim Rejections - 35 USC § 103

15. **Claim 27** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino
US 4,733,654 in view of Judet et al US 5,591,168 and Engelhardt et al US 4,805,607.

Marino discloses the claimed invention as discussed above with a buttress plate with holes and pins/nails with smooth parts (#19 and #21, #17 as seen in Fig 3) but does not specifically disclose a buttress plate with a plurality of barrels and large and small holes.

However, Judet teaches a buttress plate with large and small holes, a plurality of barrels, which allow for gliding hip pins with a smooth sliding part (as seen in Fig below), wherein the barrel provides a continues smooth gliding surface (see Col 2 lines 1—15).



be obvious that the proximal holes of the nail of Marino would match that of the large holes with barrels, wherein the sliding pin would correspond with the large holes of the plate and proximal holes of the nail since the pins are used and oriented to treat fractures in the femur (see Col 1 lines 60-67, Col 2 lines 1-5 in Marino and Fig 3 and Col 1 lines 10-11, 15-19, 64-67 in Judet).

However, Marino and Judet do not disclose the sliding hip pin has a triflanged part.

However, Engelhardt discloses a pin/nail with a triflanged part (#26 as seen in Figs 5, 7 and 9).

It would have been obvious to one having ordinary skill in the art to modify the proximal sliding hip pin Marino and Judet to include a tri-flanged tip as taught by Engelhardt because it allows bone contact along three very thin flanges of metal that are equally spaced, where the leading end of each flange is a sharp point that upon nail impaction cuts into the bone and provides a self broaching mechanism (see Col 2 lines 11-16) and that the edges of the flanges digging into the bone reduce the ability of the nail to undesirably rotate inside the bone or the individual bone fragments to rotate relative to the nail or to each other (see Col 4, lines 14-18).

16. **Claims 2-3, 7-8, 14-15, 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marino US 4,733,654, Judet et al US 5,591,168 and Engelhardt et al US 4,805,607, as applied to claim 27 above, and in further view of Brumfield US 5,562,666.

Marino, Judet, and Engelhardt disclose the claimed invention as discussed above, but does not specifically disclose the length of the nail being a short version and where the knee end has a curvature.

However, it would have been an obvious matter of design choice provide the nail in a short length version, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Nevertheless, Brumfield teaches it is known to have a short length version of an intramedullary nail of short length version (#110) depending on the patient, where one would not to ream the entire length of the femoral marrow channel if there is no trauma to that area (see Col 5 lines 55-65), wherein the knee end has a curvature to align with the marrow canal of the femur (see Col 3 lines 18-24).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the length of the nail of Marino to be short in length and the knee end to have a curvature as taught by Brumfield above because one would not to ream the entire length of the femoral marrow channel if there is no trauma to that area (see Col 5 lines 55-65), wherein the curvature aligns with the marrow canal of the femur (see Col 3 lines 18-24).

With regards to **Claim 3**, see fig above in Claim 1, where the targeting device is short and compact and can be removable to not obstruct imaging (see Fig above and see Col 3 lines 14-59).

With regards to **Claim 7**, a first distance between a tip of the connecting end and proximal holes is kept at an X value and a second distance between a pair of proximal holes is kept at Y value, wherein X and Y are in millimeters (see Fig above in Claim 1 where any number of distances in X can be made between the connecting end and the holes and that the proximal holes are at a distance Y, where the distance between any given point can always be measured in millimeters, wherein the examiner notes that placement and orientation of the sliding pins would obviously be dependent on the patient's need, where it would be capable of engagement in the calcar portion and neck portion and capable of preventing cut through of the sliding hip pins from the neck portion to the head portion of the femur). The examiner further notes that it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

With regards to **Claim 8**, the intramedullary nail is of a short length version (see above), where a distance between the tip of the connecting end and second plurality of distal holes is kept at a Z value in millimeters and the second plurality of distal holes correspond with the first plurality of distal holes of the nail (as seen in Fig above in claim 1 and where there is a distance between the connecting end and the distal holes that can be measured in millimeters).

With regards to **Claim 14**, the distance between the tip of the tip of the connecting end of the nail and the first plurality of proximal holes is kept at a third distance X1 value, and a fourth distance between a pair proximal holes is kept at Y1 is kept in millimeters (see Fig above in claim 1 where a distances X1 and Y1 can be

formed, where the distance between any two points can be measured in millimeters and the examiner notes that placement and orientation of the sliding pins would obviously be dependent on the patient's need, where it would be capable of engagement in the calcar portion and neck portion and capable of preventing cut through of the sliding hip pins from the neck portion to the head portion of the femur).

With regards to **Claim 15**, where the nail is of a short length, mounted on the targeting device (see above and Fig in Claim 1), where the connecting end a first plurality of distal holes is at a distance Z1 value in millimeters and where the distal holes of the target device correspond to the distal holes of the nail (see Fig above in claim 1).

With regards to **Claim 18**, see rejection for claim 27, where the sliding pin has a head part, a smooth part and a triflanged part with scalloped three flat equal surfaces (see #26, Figs 5, 7, 9 where the triflanged part has three equal surfaces

With regards to the flat surfaces span up to 15 to 50mm, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the flat surfaces span up to 15 to 50mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Further more, it would have been an obvious matter of design choice to construct the flat surfaces span up to 15 to 50mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as

being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

17. **Claims 21, 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marino US 4,733,654, Judet et al US 5,591,168, Engelhardt et al US 4,805,607, Brumfield US 5,562,666, as applied to claims 2, 18 above, in further view of Middleton et al US 2003/0083662.

Marino, Judet, Engelhardt, and Brumfield disclose the claimed invention as discussed above but does not disclose the sliding pin with a central cannulation and a plurality of holes.

However, Middleton discloses a pin with a central cannulation (#192) and plurality of holes (#134 as seen in Figs 11a-11c).

It would have been obvious to one having ordinary skill in the art to modify the triflanged part of Marino, Judet, Engelhardt, and Brumfield to include the holes (#134) and central cannulation of Middleton because the holes (#134) and central cannulation are adapted for the flow of in-situ hardenable material (see paragraph 34), wherein the material is bone cement (see paragraph 37) to help in fixation of the pin within bone (see paragraph 5) wherein the holes would not hamper the sliding of the smooth part.

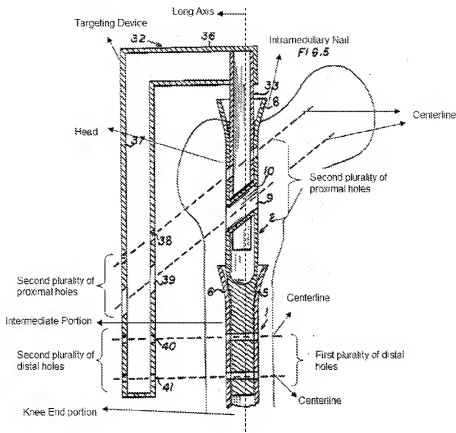
With regards to the diameters of the holes, it would also have been obvious to one having ordinary skill in the art to have holes of at least 2mm due to the small space within the body to sufficiently supply material through the holes.

It would also have been obvious to one having ordinary skill in the to have holes of at least 2mm, since it has been held that discovering an optimum value of a result effective

variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

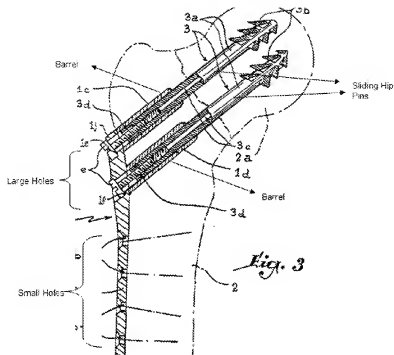
18. **Claim 28** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino US 4,733,654 in view of Judet et al US 5,591,168 and Engelhardt et al US 4,805,607.

Marino discloses an implant assembly comprising a unitary intramedullary nail comprising a head, intermediate portion, knee end portion, a long axis with a first plurality of proximal holes and a first plurality of distal holes, each with a centerline that corresponds with a block of second plurality of proximal holes and a block of a second plurality of distal holes of a targeting device connectable to the nail, wherein the proximal centerline intersects the long axis and defines a plane of centre for each of the plurality of distal holes, the distal centerline intersect the long axis at a substantially perpendicular angle also defining a plane of centre, wherein the plane of centers intersect with each other and where proximal sliding hip pins and distal locking screws is engagable to the proximal and distal holes of the nail, respectfully, without rotating the targeting device. (as seen in Fig below as well as in Fig 1).



Marino discloses the claimed invention as discussed above with a buttress plate with holes and pins/nails with smooth parts (#19 and #21, #17 as seen in Fig 3) but does not specifically disclose a buttress plate with a plurality of barrels and large and small holes.

However, Judet teaches a buttress plate with large and small holes, a plurality of barrels, which allow for gliding hip pins with a smooth sliding part (as seen in Fig below), wherein the barrel provides a continues smooth gliding surface (see Col 2 lines 1—15).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plate of Marino with that of Judet as discussed above because it applies a known technique to a known device ready for improvement to yield predictable results of guiding a screw/pin to be positioned under tension to draw the cephalic sphere nearer the body of the femur (see Col 1 lines 15-19), wherein it would be obvious that the proximal holes of the nail of Marino would match that of the large holes with barrels, wherein the sliding pin would correspond with the large holes of the plate and proximal holes of the nail since the pins are used and oriented to treat fractures in the femur (see Col 1 lines 60-67, Col 2 lines 1-5 in Marino and Fig 3 and Col 1 lines 10-11, 15-19, 64-67 in Judet).

However, Marino and Judet do not disclose the sliding hip pin has a triflanged part.

However, Engelhardt discloses a pin/nail with a triflanged part (#26 as seen in Figs 5, 7 and 9).

It would have been obvious to one having ordinary skill in the art to modify the proximal sliding hip pin Marino and Judet to include a tri-flanged tip as taught by Engelhardt because it allows bone contact along three very thin flanges of metal that are equally spaced, where the leading end of each flange is a sharp point that upon nail impaction cuts into the bone and provides a self broaching mechanism (see Col 2 lines 11-16) and that the edges of the flanges digging into the bone reduce the ability of the nail to undesirably rotate inside the bone or the individual bone fragments to rotate relative to the nail or to each other (see Col 4, lines 14-18).

Response to Arguments

19. Applicant's arguments with respect to claims above have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733